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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,043	11/17/2003	Richard M. Chesbrough	289-PDD-07-31 US	4168
96000	7590	06/02/2010	EXAMINER	
C. R. Bard, Inc. Bard Biopsy 1415 W. 3rd St. Tempe, AZ 85281			WEATHERBY, ELLSWORTH	
			ART UNIT	PAPER NUMBER
			3768	
			NOTIFICATION DATE	DELIVERY MODE
			06/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/707,043	Applicant(s) CHESBROUGH ET AL.	
	Examiner ELLSWORTH WEATHERBY	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-47 and 49-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-47 and 49-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 13, 16 and 38 are objected to because of the following informalities:

Regarding claim 13, there is not antecedent basis for the limitation "the wire". Regarding claims 16 and 38, the claims do not provide the necessary structural limitation to achieve the claimed function, "...automatically retracts...". That is, the claims do not appear to impart any additional structural limitations over the parent claim. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-47 and 49-75 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/907,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present application and the '906 application claim a localization marking device comprising a cannula and an actuator where movement of the actuator retracts the cannula to expose the marking device to the tissue. The present application refers to a localization wire instead of the '906 application's marking device and does not expressly teach a stylet having a stylet distal end. However, the Examiner stands that it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the present invention to include a stylet as a means to prevent the localization wire from becoming lodged in the retractable cannula.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 6-12, 14-15, 36-37, 49-55, 60-62, and 68-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer et al. (USPN 5,127,916) in view of Gillick et al. (Pub. No.: 2003/0028236).

6. Spencer et al. (hereinafter Spencer) teaches an apparatus for percutaneously implanting a localization wire within a tissue mass or at a biopsy site (Abstract, Figs. 1-18), comprising: a cannula 11 defining a lumen (e.g. defined by inner wall 59) having a sharpened distal end 55 forming an insertion tip (col. 6, ll. 8-21); an imagable localization wire 12', 80, 80' located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position (col. 6, ll. 45-62), wherein the localization wire is adapted to hold the marker in the tissue mass using a barb 13 integrally formed from the localization wire (col. 8, ll. 31-67); and a means for operating the cannula between a charged condition and a discharged condition to retract the cannula to expose the distal end of the localization wire to the tissue mass, where upon

retraction the localization wire extends beyond the distal end of the cannula (col. 8, ll. 31-67). Spencer further teaches that the cannula comprises multiple spaced imageable portions (col. 9, ll. 24-40; Fig. 9, ref. 58). Spencer further teaches that the at least one anchor comprises a set of opposing anchors that are radially offset 36, 13 (Figs. 15-16A). Spencer also teaches positioning the needle assembly using an imaging system for locating one of the cannula and the localization wire in the tissue mass (col. 6, ll. 51-67). Spencer also teaches that during the retraction of the cannula an anchor is embedded into the tissue at a predetermined location (col. 7, ll. 1-19). Spencer also teaches markings on the localization wire (col. 4, ll. 25-24).

7. Spencer does not expressly teach an actuator in operable communication with the cannula and operable between a charged condition and a discharged condition to retract the cannula to expose the distal end of the localization wire to the tissue mass.

8. In a related field of endeavor, Gillick et al. (hereinafter Gillick) teaches a control device and mechanism deploying a self-expanding medical device into a body cavity (Abstract; Figs. 1-10). Here, Gillick teaches a means for exposing a recessed instrument to a target site by retracting an outer sheath (See Fig. 7). Gillick goes on teaching an actuator in operable communication with the cannula and operable between a charged insertion condition and a discharged condition to retract the cannula to expose the distal end of the medical instrument to the tissue mass (Abstract; 0010; 0012; 0038; Figs. 12-13). Here, Gillick teaches that the actuator comprises a slide that is manually moved by the user from the charged condition to the discharged condition to retract the cannula relative to the expandable medical device (0040; 0042). Gillick also

teaches a handle defining a hollow interior and an end, with the cannula being slidable mounted to the end (Fig. 4).

9. Because both Spencer and Gillick teach the retraction of an outer sheath to expose a working end, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the percutaneous marking apparatus of Spencer with the actuator of Gillick. The motivation to modify Spencer in view of Gillick would have been to provide a single-handed means for retraction of an outer sheath.

10. Claims 16-35, 38-47, 56-59, 63-67 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer et al. (USPN 5,127,916) in view of Gillick et al. (Pub. No.: 2003/0028236) as applied to claims 1, 14, 36, 37 and 60 above, and further in view of Niezink et al. (USPN 5,273,532).

11. The localization wire implanting apparatus of Spencer in view of Gillick teaches all the limitations of the claimed invention except for expressly teaching that the actuator automatically retracts the cannula relative to the localization wire. Spencer in view of Gillick also does not expressly teach that the apparatus comprises a handle having a base mounting a proximal end of the cannula, and a grip slidably mounted to the base for movement between first and second positions. Spencer in view of Gillick also does not expressly teach that the localization wire and the cannula are contained entirely within the cannula and the handle. Spencer in view of Gillick also does not expressly teach a trigger pivotally mounted to the handle and includes a finger that abuts a collar. Spencer in view of Gillick also does not expressly teach a key and keyway.

12. In a related field of endeavor, Niezink et al. (hereinafter Niezink) teaches an injector for hypodermically implanting an object in a living being (Abstract; Figs. 1-4E). Here, an actuator automatically retracts the cannula relative to the implantable device (col. 5, ll. 43-57). Niezink discloses that the actuator comprises a biasing element (21) coupled to the cannula to move the cannula from insertion position to the implant position (See: Figs. 4A-E). Niezink also teaches a trigger operable between a ready position and a release position for controlling the operation of the biasing element, where movement of the trigger from the ready position to the release position releases a spring (21) from a compressed position to an expanded state to move the cannula from the insertion position to the implant position (Figs. 4A-E; refs. 16 and/or 22). Niezink also teaches a handle defining a hollow interior and an end, with the cannula being slidably mounted to the end (col. 5, ll. 32-41: See distal end of housing 25). Niezink further teaches that the handle comprises a grip and a base, with the grip being slidably mounted to the base for movement between a first position, where the cannula and the localization device are substantially received within the grip, and a second position, where the cannula and localization wire are substantially exterior to the grip (See Figs. 4A-4E). As can be seen in Fig. 4B, when the grip is moved to the second position, the actuator (ref. 21) is moved to the charged position. Niezink also teaches that the localization device and the cannula are located within the handle (col. 5, ll. 5-25; Fig. 1-2B). Niezink also teaches a collar (ref. 20) extending from cannula (ref. 3) wherein a trigger (refs. 12, 16, 22) is pivotally mounted to the handle and includes a finger that abuts the collar when the trigger is in the ready position, and can be pivoted to the

release position to remove the finger from abutting with the collar to release the spring (See; Figs. 2D-2E, 4D-4E). Here, the Examiner stands that this is an obvious variation of the claimed trigger operated keyway shaped for receiving key, and wherein the key is unaligned from the keyway when the actuator is in the charged condition and aligned when the actuator in the discharged condition both are equivalent means for achieving the function of preventing the unintentional discharge of the biasing element.

13. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the retractable sheath style deployment of medical devices of Spencer in view of Gillick with the automated retraction of Niezink. The motivation to modify Spencer in view of Gillick with Niezink would have been to improve the repeatability and safety of the implantation procedure.

14. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer et al. (USPN 5,127,916) in view of Gillick et al. (Pub. No.: 2003/0028236) as applied to claim 12 above, and further in view of Negus et al. (USPN 6,241,665).

15. Spencer in view of Gillick teaches all the limitations of the claimed invention except for expressly teaching that the imagable portion comprises a change in contour of the wire.

16. In a related field of endeavor, Negus et al. (hereinafter Negus) teaches a percutaneous mapping system comprising a plurality of spaced imaging markers (Abstract; Figs. 1-12). Here, Negus teaches that upon injection the wire may be torqued

so that the imaging markers are pressed against a cavity wall (col. 4, ll. 13-37). Negus also teaches using various shapes for distinction of multiple markers (col. 3, ll. 20-33).

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the retractable sheath style deployment of medical devices of Spencer in view of Gillick with the multiple shaped markers along a wire of Negus. The motivation to modify Spencer in view of Gillick with Negus would have been to aid in the determination of orientation or to improve visibility of the implanted device.

Response to Arguments

18. Applicant's arguments, see Pre-Brief Conference Request, filed 01/15/2010, with respect to the rejection(s) of claim(s) 1-4, 6-26, 30-43, 47 and 49-75 under Foerster et al. '328 in view of Makower et al. '063 and claims 27-29 and 44-46 under Foerster et al. '328 in view of Makower et al. '063 and Truckai et al. '520 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Spencer et al. '916 in view of Gillick et al. '236.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number

is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768